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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,191	11/25/2005	Lawrence Rosenberg	FC 14647-35	1534

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/558,191	ROSENBERG, LAWRENCE	
	Examiner	Art Unit	
	Ralph Gitomer	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 13-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment received 1/14/08 has been entered and claims 1-4, 13-29 are considered here. The amended abstract is acceptable.

The claimed method has two parts, growing pancreatic cells in a specific manner and then testing agents to induce differentiation into islet cells.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts.

Roberts (6,436,704) entitled "Human Pancreatic Epithelial Progenitor Cells and Methods of Isolation of Use Thereof" teaches in column 3 line 39, human pancreatic cells were grown in F12/DMEM medium. In column 8 first paragraph, the cells are cultured with cholera toxin and various growth factors. In column 9 line 32, F12/DMEM is the growth medium. In column 10 line 12, epidermal growth factor is included in the medium. In column 12 last two paragraphs, the cells can be used for drug discovery. The pancreatic progenitor cells have the capacity to differentiate into endocrine cells. In column 14 last paragraph bridging to column 15, using the cells for drug discovery where the pre-differentiated multipotent pancreatic progenitor cells are targets for drug development to promote differentiation of the cells to islet cells for treating diabetes is discussed.

The claims differ from Roberts in that they have been newly amended to read the initial cells are dedifferentiated where Roberts employed pre-differentiated cells.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to start with dedifferentiated cells because Roberts teaches that pre-differentiated cells would work and no functional distinction is seen. It is known that cells can be dedifferentiated and then later differentiated into a different functional form, in this case from duct cells to islet cells, both of which come from the same progenitor cells.

Applicant's arguments filed 1/14/08 have been fully considered but they are not persuasive.

Applicant argues that the cells of Roberts are of fetal origin where the present cells are adult or post-natal cells. The cells of Roberts are undifferentiated and not dedifferentiated cells.

It is the examiner's position that the claims as amended do not require the cells to be post-natal or adult cells. And no functional difference is seen in the cells of Roberts and those presently claimed where the same method is applied for the same function to cells that would be expected to behave in the same manner.

Claims 1-4, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Korsgren and Oberg-Welsh in view of Bonner-Weir.

Korsgren (Upsala J Med Sci) entitled "In vitro Screening of Putative Compounds Inducing Fetal Porcine Pancreatic Beta Cell Differentiation: Implications for Cell Transplantation in Insulin Dependent Diabetes Mellitus" teaches on page 43 Table 1, the insulin excretion of fetal pancreatic cells treated with a number of substances to determine which best induced beta cell differentiation.

Oberg-Welsh (Pancreas) entitled "Effects of Certain Growth Factors on In vitro Maturation of Rat Fetal Islet Like Structures" teaches on page 334 last paragraph bridging to page 335, investigating various substances to differentiate beta cells from precursor cells. On page 336 Table 1 lists data from various substances to change insulin secretion.

The claims differ from the above references in that they do not specify the pancreatic cells are first grown on Matrigel before testing compounds to increase differentiation.

Bonner-Weir (PNAS) entitled "In vitro Cultivation of Human Islets From Expanded Ductal Tissue" teaches in the abstract, culturing the human islets with Matrigel to form 3D structures of ductal cysts with clusters of pancreatic endocrine cells budded. The cultures were stimulated with glucose. On page 7999 column 2 the medium was DMEM/F12. On page 8001 column 1 first full paragraph, keratinocyte growth factor stimulated growth.

It would have been obvious to one of ordinary skill in the art at the time of the invention to grow the cells by the method of Bonner-Weir prior to testing the cells for compounds to increase differentiation as taught by both Korsgren and Oberg-Welsh because Bonner-Weir grows the cells in order to get them to make insulin and stimulates them to do so, the same reason for the methods of the primary references. Further, both the claimed method of growing the cells and the method of determining compounds to increase differentiation are old. To combine the two methods would have been obvious because one would have more cells in which to test if one cultured the cells prior to testing them. This concept is well known in drug testing and microbiology in general.

Applicant's arguments filed 1/14/08 have been fully considered but they are not persuasive.

Applicant argues that the cells of the references are of fetal origin where the presently claimed cells are adult or post-natal origin. The reliability of the transdifferentiated cells of the references is unknown. And Bonner-Weir discards the islet cells. It is not obvious to achieve dedifferentiation of post-natal islet cells.

The claims have been amended to delete the cells are adult or post-natal origin. No reliability of the cells in the present method is claimed. Bonner-Weir was cited to show cultivating cells on Matrigel and is properly combinable with the primary references for that feature.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 13-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1 "with at least biopotentiality" is not found in the specification as originally filed and is not an art recognized term.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 13-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 "bipotentiality" is not an art recognized term. Claim 1 is not understood as amended where the preamble is directed to a method for screening agents that induce neogenesis or transdifferentiation, but in step (c) the agent is determined to induce differentiation to insulin producing cells. In claim 1(a) ductal cells are employed but the preamble includes islet cells. What is determined is unclear and would be

critical to the invention. And there is no correlating step to producing insulin and the agent which is screened. Claims 25 and 29 contain improper Markush terminology.

This application contains claims 5-12 drawn to an invention nonelected with traverse in the reply filed on 8/31/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ralph Gitomer
Primary Examiner
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